IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9133

Bartle, J. August 20, 2013

Bethany Massey ("Ms. Massey" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2008, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gary L. Murray, M.D. Based on an echocardiogram dated February 18, 1999, Dr. Murray attested in Part II of Ms. Massey's Green Form that she suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[3] Based on such findings,

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Murray also attested that claimant suffered from a reduced ejection fraction in the range of 50% to 60%. This condition is not at issue in this claim.

claimant would be entitled to Matrix A-1, Level III benefits in the amount of $879,943.[4]

Dr. Murray also attested that claimant did not have a rheumatic mitral valve. Under the Settlement Agreement, the presence of a rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Evidence of a rheumatic valve is defined by the Settlement Agreement as "doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion." See id. As the Trust does not contest claimant's entitlement to Level III Matrix Benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In June, 2008, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists.[5] In audit, Dr. Oliner concluded that there was no reasonable medical basis for Dr. Murray's finding that claimant did not have a rheumatic mitral valve. Specifically, Dr. Oliner stated:

> There is definite anterior leaflet diastolic mild doming, consistent with rheumatic mitral

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4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

5. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 24, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level III claim, pursuant to the PPP, the Trust audited Ms. Massey's claim.

> valve disease. Both leaflet tips are thickened, consistent with rheumatic mitral valve disease. There is submitral apparatus involvement. The surgical report states the intraoperative [transesophageal echocardiogram] confirmed a rheumatic looking valve. At surgery, the mitral valve was found to be scarred, with the anterior leaflet pulled inward and the papillary heads fused to the back of the valve. The [transesophageal echocardiogram] report from 10/5/01 states the mitral valve was rheumatic in morphology.

Based on Dr. Oliner's finding, the Trust issued a post-audit determination that Ms. Massey was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that her February 18, 1999 echocardiogram did not demonstrate a rheumatic mitral valve and that the other materials submitted with her claim, including an October 5, 2001 echocardiogram, an October 5, 2001 operative report, and an October 6, 2001 pathology report did not establish that Ms. Massey had rheumatic mitral valve disease at the time of her mitral valve replacement surgery. In support, claimant submitted a verified statement of Manoj R. Muttreja, M.D. Dr. Muttreja stated, in pertinent part, that:

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Massey's claim.

In his Report of Auditing Cardiologist Opinion Concerning Green Form Questions at Issue, Dr. Oliner stated, "There is definite anterior leaflet diastolic mild doming, consistent with rheumatic mitral valve disease." Presumably this observation pertains to the 02/18/1999 [transthoracic echocardiogram]. As an initial matter, this statement is inconsistent in its conflation of "mild" and "definite." The interpreting cardiologist of this study did not mention these findings or come up with the overall conclusion that Ms. Massey had the findings of a rheumatic valve in his report of this study. In my review of the videotape, I saw perhaps only mild doming in some off-axis views. The mild doming was inconsistent throughout the study and did not appear in any standard views and, in my opinion, was certainly not consistent with the findings of a rheumatic valve. Moreover, this echocardiogram contained additional views during the stress component. No doming or restriction of the anterior leaflet (hockey-sticking) occurred during these additional stress images of the echocardiogram when the patient reached her peak goal heart rate. This finding would definitely be present and blatantly obvious if Ms. Massey truly had a rheumatic mitral valve. Dr. Oliner also noted that "both leaflet tips are thickened, consistent with rheumatic mitral valve disease." However, leaflet tip thickening is not a finding specific to rheumatic heart disease and is present in multiple different pathologies.

Dr. Oliner also referenced the surgical report and intraoperative [transesophageal echocardiogram] in his report. First, I would like to point out that a rheumatic heart valve cannot be diagnosed by the surgeon. A surgeon can only see the gross view of the valve during his operation. The gross findings of a rheumatic valve are very nonspecific and can be seen in multiple different pathologies. Such a diagnosis can be suggested by echocardiography and definitely made by pathology. The report of the 10/05/2001 intraoperative [transesophageal echocardiogram] while indeed

stating that the mitral valve appears "rheumatic in morphology" also states that posterior leaflet is fixed but the anterior leaflet opening appears normal. Again, one would see restricted motion of the anterior leaflet in the case of a rheumatic mitral valve and not just the involvement of a portion of the valve. The surgeon found the valve to be scarred with the anterior leaflet pulled inward and the papillary heads fused to the back of the valve. Such findings are not specific to rheumatic mitral valve, and could, in fact, be *more* indicative of lesions induced through fenfluramine exposure. I have seen multiple valves like the one described by this surgeon in my experience that have been caused by fenfluramine exposure and not rheumatic heart disease.

Interestingly, Dr. Oliner appears to have completely disregarded the 09/07/2001 [transesophageal echocardiogram] and the surgical pathology report. I have reviewed the videotape of the 09/07/2001 [transesophageal echocardiogram]. Although the report of the [transesophageal echocardiogram] states the mitral valve appears to be normal, the valve appears thickened and there is some restriction of the posterior leaflet. However, there is no heavy calcification or doming which would be present in the case of a rheumatic mitral valve.

Most importantly, the surgical pathology report contains no indication whatsoever that her excised mitral valve was rheumatic. The pathologist's diagnosis is "atherosclerosis, calcification and myoxid degeneration." Her findings are not consistent with a diagnosis of rheumatic mitral valve disease. Rheumatic valve disease would have been mentioned as a matter of course had it been indicated by the pathologist's findings.

In summary, it is my opinion from the review of the materials provided, that Ms. Massey did not have a rheumatic mitral valve before the mitral valve replacement. Dr. Oliner's finding that she exhibited a rheumatic valve appears to have been based

primarily on the surgeon's comments rather than pathological evidence and evidence from the echocardiograms.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Oliner submitted a declaration again concluding that there was no reasonable medical basis for the attesting physician's determination that there was no evidence of a rheumatic mitral valve. Dr. Oliner explained:

> 11. During my review of this Claim at audit, I stated that the February 18, 1999 echocardiogram demonstrates anterior leaflet diastolic mild doming and thickening of both leaflet tips, consistent with rheumatic mitral valve disease. Upon review of the February 18, 1999 echocardiogram study at Contest, I again observed definite mild diastolic doming in the parasternal long axis view, which *is* a standard view. The diastolic doming is both definite and mild. These findings are consistent with rheumatic disease and support a diagnosis of rheumatic mitral valve disease.
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> 12. At Contest, I also reviewed the September 7, 2001 [transesophageal echocardiogram] study. This study shows thickened and partially calcified mitral leaflets with mild diastolic doming and chordal shortening. These findings are suggestive of rheumatic mitral valve disease.
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> 13. In addition to echocardiographic evidence of rheumatic mitral valve disease, Claimant's medical records support a diagnosis [of] rheumatic mitral valve disease. The October 5, 2001 [transesophageal echocardiogram] report states the mitral valve "appears rheumatic in morphology," and the October 5, 2001 operative report

> states that, on direct visualization, the mitral valve appeared rheumatic in morphology. Further, the October 8, 2001 surgical pathology report states that the mitral valve was "mildly thickened and fibrotic", with "focal slight thickening and fusion of the chordae tendinae." Microscopic findings were "focal calcification, atherosclerosis and myoxid degeneration." While the surgical pathology report does not expressly identify rheumatic valve disease, the surgical pathologic findings are consistent with rheumatic mitral valve disease.

The Trust then issued a final post-audit determination, again determining that Ms. Massey was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Massey's claim should be paid. On June 4, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8182 (June 4, 2009).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 26, 2009. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she did not have a rheumatic mitral valve. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Massey reasserts the arguments she made in contest. In response, the Trust argues that Dr. Oliner properly determined that there was echocardiographic evidence of rheumatic mitral valve on claimant's various echocardiograms. In addition, the Trust contends that Ms. Massey cannot overcome the echocardiographic evidence of rheumatic mitral valve by reference to a nonspecific pathology report.

The Technical Advisor, Dr. Vigilante, reviewed Ms. Massey's claim and concluded that there was no reasonable medical basis for the attesting physician's finding. Specifically, Dr. Vigilante observed:

> I reviewed the Claimant's echocardiogram of February 18, 2009. This was both a resting and stress study.... This was a good quality study with the usual echocardiographic views obtained. I reviewed all images of the mitral valve and mitral apparatus in real-time and I digitized these images and reviewed them in multiple loops. Both mitral leaflets were moderately thickened. There was increased refractoriness of echoes at the tips of both leaflets consistent with focal calcification of the mitral valve leaflet tips. There was classic doming of the anterior mitral leaflet seen in the parasternal, apical four chamber and apical two chamber views. Significant mitral stenosis was not present. The motion of the anterior mitral leaflet had a "hockey stick" appearance. Doming and the "hockey stick" appearance of the anterior mitral leaflet were due to commissural fusion. The belly of the anterior leaflet was more pliable and moved further out than the leaflet tip causing this abnormal motion. There was significant thickening of the mitral cords particularly those cords that were attached to the mid portion of the anterior mitral

leaflet. These echocardiographic findings are classic for rheumatic involvement of the mitral valve seen in the parasternal long axis view, apical four chamber and apical two chamber views. The findings at the time of cardiac surgery by Dr. Petracek on October 5, 2001 that included a scarred down mitral valve as well as papillary muscle head fusion to the back of the valve are also classically seen in rheumatic mitral valvular disease....

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I also reviewed the Claimant's transesophageal echocardiogram of September 7, 2001.... This was a reasonable quality study with the usual [transesophageal echocardiogram] views obtained. I reviewed all images of the mitral valve and mitral apparatus in real-time and digitized these images and reviewed them in multiple loops. Once again, it was noted that both mitral leaflets were moderately thickened and there was classic doming of an anterior mitral leaflet seen particularly at 25 degrees, 141 degrees, and 146 degrees. The belly of the mitral leaflet was more pliable and moved further out than the leaflet tip causing this abnormal doming motion. This abnormal motion was caused because of commissural fusion. There was focal calcification at the tips of the mitral leaflets. Subvalvular chordal thickening and fusion were noted....

After analyzing both echocardiogram tapes and reviewing the medical records, I reviewed Dr. Muttreja's letter of February 19, 2009. This cardiologist was incorrect in stating that there was only mild doming in some off-axis views and that the mild doming was inconsistent throughout the study. Indeed, doming was obvious in multiple views. I also disagree with Dr. Muttreja's statement that the pathologist would have mentioned rheumatic valve disease upon examination of the tissue. Based on my review of the echocardiograms and accompanying medical records, it would be impossible for a reasonable echocardiographer to conclude that the mitral valve was not a structurally rheumatic valve.

In response to the Technical Advisor Report, claimant argues that Dr. Muttreja's findings were correct and supported by the auditing cardiologist, who found only mild doming on the February 18, 2009 echocardiogram. Ms. Massey also contends Dr. Vigilante erred because he did not address Dr. Muttreja's opinion that doming or restriction of the anterior leaflet would have appeared in the stress portion of her echocardiogram if she had rheumatic mitral valve. In addition, Ms. Massey asserts that the surgical findings do not support a finding of rheumatic mitral valve because, as Dr. Muttreja explained, these findings "could very well be consistent with other disease processes ... caused by fenfluramine exposure." Finally, claimant argues that Dr. Vigilante inappropriately dismissed the absence of a rheumatic mitral valve finding in the pathology report.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. The Settlement Agreement specifically provides, in pertinent part, that a claimant will receive reduced Matrix Benefits if there is:

> M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease.

Settlement Agreement § IV.B.2.d.(2)(c)ii)e) (emphasis added). Here, the auditing cardiologist determined, and claimant does not adequately contest, that her echocardiograms reveal evidence of a

rheumatic mitral valve. In particular, Dr. Muttreja noted, "In my review of the [February 18, 1999] videotape, I saw perhaps only mild doming in some off-axis views." He also stated, "Although the report of the [September 7, 2001 echocardiogram] states the mitral valve appears to be normal, the valve appears thickened and there is some restriction of the posterior leaflet."

Similarly, Dr. Oliner determined that claimant's February 18, 1999 transthoracic echocardiogram demonstrates "definite mild diastolic doming in the parasternal long axis view" and that claimant's September 7, 2001 echocardiogram "shows thickened and partially calcified mitral leaflets with mild diastolic doming and chordal shortening." The Technical Advisor also reviewed claimant's February 18, 1999 and September 7, 2001 echocardiograms and concluded that each demonstrated classic doming of the anterior leaflet and commissural fusion.

To meet her burden, claimant notes that the surgical pathology report does not contain any indication that her mitral valve was rheumatic. In addition, she relies on Dr. Muttreja's opinion the echocardiographic characteristics demonstrated on her echocardiograms are not consistent with a finding of rheumatic mitral valve. Thus, according to claimant, there is a reasonable medical basis for the attesting physician's conclusion that Ms. Massey did not have a rheumatic mitral valve. Claimant's reliance on the pathology report and Dr. Muttreja's opinion, however, are misplaced.

Under the Settlement Agreement, if there is echocardiographic evidence of rheumatic valve disease, a claim will be reduced to the B-1 Matrix, except where a Board-Certified Pathologist examines the mitral valve tissue and determines that there is no evidence of rheumatic valve disease. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). As noted, Dr. Muttreja concedes that claimant's echocardiograms contain evidence, as defined by the Settlement Agreement, of a rheumatic mitral valve. Although claimant asserts that the absence of any reference to rheumatic valve disease in her pathology report supports her claim, the opposite is true. Only a specific finding by a Board-Certified Pathologist that the mitral valve tissue does not reveal evidence of rheumatic valve disease will allow a claimant to avoid application of this reduction factor. See, e.g., Mem. in Supp. of PTO No. 7466 at 9 (Oct. 10, 2007); Mem. in Supp. of PTO No. 7467 at 6-7 (Oct. 10, 2007).

Finally, we reject claimant's argument that she is entitled to Matrix A-1 benefits because the condition of her mitral valve is more consistent with exposure to Diet Drugs than rheumatic valve disease. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimant is required to show that she meets, or in the case of the presence of reduction factors, does not meet, the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover

> Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse is also true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. As the Settlement Agreement unequivocally requires a mitral valve claim to be reduced to Matrix B-1 if claimant's echocardiogram reveals evidence of a rheumatic mitral valve and a Board-Certified Pathologist has not provided a contrary determination after examination of the mitral valve tissue, we must apply the Settlement Agreement as written. Accordingly, claimant's assertion that the condition of her mitral valve was caused by her ingestion of Diet Drugs is irrelevant to the issue before the court. Because claimant does not adequately contest that her echocardiograms revealed evidence of a rheumatic mitral valve and a Board-Certified Pathologist has not provided a contrary determination, the Settlement Agreement requires that Ms. Massey's claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have a rheumatic mitral valve. Therefore, we will affirm the Trust's denial of Ms. Massey's claim for Matrix A-1 benefits.